# UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

ALI ELBANEH AND SUBHIA ELBANEH,

Plaintiffs,

**CASE NUMBER:** 

1:11-CV-02680-ENV-JO

v.

JURY TRIAL DEMANDED

ZIMMER, INC., ZIMMER HOLDINGS, INC., ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC.,

Defendants.

# ANSWER TO FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL BY DEFENDANTS ZIMMER, INC., ZIMMER HOLDINGS, INC., AND ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC.

The defendants, Zimmer, Inc., Zimmer Holdings, Inc., and Zimmer Orthopaedic Surgical Products, Inc. (collectively, the "Zimmer Defendants"), respond to the First Amended Complaint And Demand For Jury Trial ("Complaint") filed by the plaintiffs, Ali Elbaneh and Subhia Elbaneh ("Plaintiffs"), as follows.

# FIRST DEFENSE

# **NATURE OF THE CASE**

- 1. The Zimmer Defendants deny the allegations in Paragraph 1 of the Complaint.
- 2. The Zimmer Defendants deny the allegations in Paragraph 2 of the Complaint.

#### **PARTIES**

- 3. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 3 of the Complaint and, therefore, deny them.
  - 4. The Zimmer Defendants admit the allegations in Paragraph 4 of the Complaint.
  - 5. The Zimmer Defendants admit the allegations in Paragraph 5 of the Complaint.

- 6. The Zimmer Defendants state that Zimmer Surgical, Inc., formerly known as Zimmer Orthopaedic Surgical Products, Inc., has its principal place of business in Dover, Ohio, but deny any remaining allegations in Paragraph 6 of the Complaint.
- 7. The Zimmer Defendants admit that Zimmer, Inc., developed, designed, tested, manufactured, distributed, marketed, and sold a variety of knee replacement products under the Zimmer NexGen brand, including the Zimmer CR-Flex. The Zimmer Defendants admit that products developed, designed, tested, manufactured, distributed, and marketed by Zimmer, Inc., are sold in multiple locations around the world, including within the State of New York. The Zimmer Defendants deny any remaining allegations in Paragraph 7 of the Complaint.

# **JURISDICTION AND VENUE**

- 8. The Zimmer Defendants admit the allegations in Paragraph 8 of the Complaint.
- 9. The Zimmer Defendants admit that Zimmer, Inc., sold products within the area that includes the Eastern District Of New York, but the Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 9 of the Complaint and, therefore, deny them.

# FACTUAL BACKGROUND KNEE REPLACEMENT BACKGROUND

- 10. Paragraph 10 of the Complaint includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 10 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.
- 11. Paragraph 11 of the Complaint includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 11

can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

- 12. Paragraph 12 of the Complaint includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 12 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.
- 13. Paragraph 13 of the Complaint includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 13 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.
- 14. Paragraph 14 of the Complaint includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 14 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.
- 15. Paragraph 15 of the Complaint includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 15 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.
- 16. The first and second sentences of Paragraph 16 of the Complaint include Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants; the third sentence is unintelligible in its use of the undefined phrase "psychical burden." To the extent Paragraph 16 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

- 17. Paragraph 17 of the Complaint includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 17 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.
- 18. Paragraph 18 of the Complaint includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 18 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.
- 19. To the extent that Paragraph 19 of the Complaint intends to suggest that any "concern" in knee revision surgery is of greater importance than the patient's health and surgical outcome, the Zimmer Defendants deny those allegations. Moreover, Paragraph 19 includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 19 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.
- 20. Paragraph 20 of the Complaint includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants, and further includes Plaintiffs' global characterization of individual patient outcomes to which it is impossible to respond on a comprehensive basis. To the extent that Paragraph 20 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.

#### ZIMMER NEXGEN CR FLEX FACTS

21. The Zimmer Defendants admit that Zimmer Manufacturing Company was founded in 1927. The Zimmer Defendants admit that Zimmer, Inc., designs and manufactures a

wide range of orthopaedic devices. The Zimmer Defendants deny the remaining allegations in Paragraph 21 of the Complaint.

- 22. The Zimmer Defendants admit that the Zimmer CR-Flex includes a design feature that safely accommodates high flexion and denies the remaining allegations in Paragraph 22 of the Complaint.
- 23. The Zimmer Defendants admit that Zimmer, Inc., manufactured, labeled, distributed, supplied, marketed, and advertised a variety of knee replacement products under the Zimmer NexGen brand, including the Zimmer CR-Flex, and further caused products under the NexGen brand to be placed in the stream of commerce throughout the United States. The Zimmer Defendants deny the remaining allegations of paragraph 23 of the Complaint.
- 24. The Zimmer Defendants admit that Zimmer, Inc., submitted regulatory filings to the United States Food & Drug Administration, which resulted in the clearance of a variety of knee replacement products sold under the Zimmer *NexGen* brand, including the Zimmer CR-Flex. The Zimmer Defendants deny the remaining allegations in Paragraph 24 of the Complaint.
- 25. The Zimmer Defendants admit that Zimmer, Inc., designed, assembled, manufactured, marketed, distributed, packaged, labeled, processed, supplied, promoted, and sold a variety of knee replacement products under the Zimmer *NexGen* brand, including the Zimmer CR-Flex, and further admit that the knee replacement products sold under the *NexGen* brand include a Package Insert containing warnings and related information regarding the products.

  The Zimmer Defendants deny the remaining allegations in Paragraph 25 of the Complaint.
- 26. The Zimmer Defendants admit that Zimmer, Inc., submitted regulatory filings to the United States Food & Drug Administration regarding a variety of knee replacement products sold under the Zimmer *NexGen* brand, including the Zimmer CR-Flex. Moreover, the Zimmer

Defendants admit that Zimmer, Inc., is subject to regulations and laws pertaining to the design, manufacture, and sale of medical devices in the United States. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 26 of the Complaint because the Plaintiffs fail to specify the laws, provisions, rules, and regulations to which they refer and, therefore, the Zimmer Defendants deny the remaining allegations in Paragraph 26.

27. The Zimmer Defendants admit that Zimmer, Inc., advertised and marketed a variety of knee replacement products sold under the Zimmer *NexGen* brand, and further admit that *NexGen* knee replacement products, including the Zimmer CR-Flex, are safe and effective in the treatment of the class of patients for which the products were intended when implanted and used as intended. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 27 and, therefore, deny them.

#### ZIMMER NEXGEN CR FLEX PROBLEMS

- 28. Paragraph 28 of the Complaint includes Plaintiffs' characterization of medical opinions that require no response from the Zimmer Defendants. To the extent that Paragraph 28 can be construed as containing allegations against the Zimmer Defendants, the Zimmer Defendants deny those allegations.
  - 29. The Zimmer Defendants deny the allegations in Paragraph 29 of the Complaint.
  - 30. The Zimmer Defendants deny the allegations in Paragraph 30 of the Complaint.
  - 31. The Zimmer Defendants deny the allegations in Paragraph 31 of the Complaint.

### **FACTUAL ALLEGATIONS**

32. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 32 of the Complaint and, therefore, deny them.

- 33. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 33 of the Complaint and, therefore, deny them.
- 34. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 34 of the Complaint and, therefore, deny them.
- 35. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 35 of the Complaint and, therefore, deny them.
- 36. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 36 of the Complaint and, therefore, deny them.
  - 37. The Zimmer Defendants deny the allegations in Paragraph 37 of the Complaint.
  - 38. The Zimmer Defendants deny the allegations in Paragraph 38 of the Complaint.
  - 39. The Zimmer Defendants deny the allegations in Paragraph 39 of the Complaint.

### **EQUITABLE TOLLING APPLICABLE STATUTES OF LIMITATIONS**

- 40. The Zimmer Defendants deny the allegations in Paragraph 40 of the Complaint.
- 41. The Zimmer Defendants deny the allegations in Paragraph 41 of the Complaint.
- 42. The Zimmer Defendants deny the allegations in Paragraph 42 of the Complaint.
- 43. The Zimmer Defendants deny the allegations in Paragraph 43 of the Complaint.

# COUNT I STRICT PRODUCTS

- 44. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
- 45. The Zimmer Defendants admit that Zimmer, Inc., developed, tested, manufactured, marketed, and sold a variety of products under the Zimmer *NexGen* brand, including the Zimmer CR-Flex, and further admit they knew that certain products would be

implanted during knee replacement surgery. The Zimmer Defendants deny the remaining allegations in Paragraph 45 of the Complaint.

- 46. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 46 of the Complaint and, therefore, deny them.
  - 47. The Zimmer Defendants deny the allegations in Paragraph 47 of the Complaint.
  - 48. The Zimmer Defendants deny the allegations in Paragraph 48 of the Complaint.
  - 49. The Zimmer Defendants deny the allegations in Paragraph 49 of the Complaint.
  - 50. The Zimmer Defendants deny the allegations in Paragraph 50 of the Complaint.
  - 51. The Zimmer Defendants deny the allegations in Paragraph 51 of the Complaint.
  - 52. The Zimmer Defendants deny the allegations in Paragraph 52 of the Complaint.
  - 53. The Zimmer Defendants deny the allegations in Paragraph 53 of the Complaint.
  - 54. The Zimmer Defendants deny the allegations in Paragraph 54 of the Complaint.

# COUNT II PRODUCTS LIABILITY – FAILURE TO WARN

- 55. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
- 56. The Zimmer Defendants admit Zimmer, Inc., developed, designed, manufactured, tested, marketed, and sold a variety of products under the Zimmer *NexGen* brand, including the Zimmer CR-Flex, but the Zimmer Defendants deny the remaining allegations in Paragraph 56 of the Complaint.
  - 57. The Zimmer Defendants deny the allegations in Paragraph 57 of the Complaint.
  - 58. The Zimmer Defendants deny the allegations in Paragraph 58 of the Complaint.
  - 59. The Zimmer Defendants deny the allegations in Paragraph 59 of the Complaint.
  - 60. The Zimmer Defendants deny the allegations in Paragraph 60 of the Complaint.

61. The Zimmer Defendants deny the allegations in Paragraph 61 of the Complaint.

# COUNT III PRODUCTS LIABILITY – DEFECTIVE DESIGN

- 62. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
- 63. The Zimmer Defendants admit that Zimmer, Inc., researched, developed, manufactured, distributed, marketed, promoted, supplied, and sold a variety of products under the Zimmer *NexGen* brand, including the Zimmer CR-Flex, but deny the remaining allegations in Paragraph 63 of the Complaint.
  - 64. The Zimmer Defendants deny the allegations in Paragraph 64 of the Complaint.
  - 65. The Zimmer Defendants deny the allegations in Paragraph 65 of the Complaint.
  - 66. The Zimmer Defendants deny the allegations in Paragraph 66 of the Complaint.
  - 67. The Zimmer Defendants deny the allegations in Paragraph 67 of the Complaint.
- 68. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 68 of the Complaint and, therefore, deny them.
  - 69. The Zimmer Defendants deny the allegations in Paragraph 69 of the Complaint.
  - 70. The Zimmer Defendants deny the allegations in Paragraph 70 of the Complaint.
  - 71. The Zimmer Defendants deny the allegations in Paragraph 71 of the Complaint.

# COUNT IV NEGLIGENCE

- 72. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
  - 73. The Zimmer Defendants deny the allegations in Paragraph 73 of the Complaint.
  - 74. The Zimmer Defendants deny the allegations in Paragraph 74 of the Complaint.

- 75. The Zimmer Defendants deny the allegations in Paragraph 75 of the Complaint.
- 76. The Zimmer Defendants deny the allegations in Paragraph 76 of the Complaint.
- 77. The Zimmer Defendants deny the allegations in Paragraph 77 of the Complaint.
- 78. The Zimmer Defendants deny the allegations in Paragraph 78 of the Complaint.
- 79. The Zimmer Defendants deny the allegations in Paragraph 79 of the Complaint.

# COUNT V BREACH OF EXPRESS WARRANTY

- 80. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
  - 81. The Zimmer Defendants deny the allegations in Paragraph 81 of the Complaint.
  - 82. The Zimmer Defendants deny the allegations in Paragraph 82 of the Complaint.
  - 83. The Zimmer Defendants deny the allegations in Paragraph 83 of the Complaint.
- 84. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 84 of the Complaint and, therefore, deny them.
  - 85. The Zimmer Defendants deny the allegations in Paragraph 85 of the Complaint.
  - 86. The Zimmer Defendants deny the allegations in Paragraph 86 of the Complaint.
  - 87. The Zimmer Defendants deny the allegations in Paragraph 87 of the Complaint.

# COUNT VI BREACH OF IMPLIED WARRANTY

- 88. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
  - 89. The Zimmer Defendants deny the allegations in Paragraph 89 of the Complaint.
- 90. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 90 of the Complaint and, therefore, deny them.

- 91. The Zimmer Defendants deny the allegations in Paragraph 91 of the Complaint.
- 92. The Zimmer Defendants deny the allegations in Paragraph 92 of the Complaint.
- 93. The Zimmer Defendants deny the allegations in Paragraph 93 of the Complaint.

# COUNT VII FRAUDULENT MISREPRESENTATION

- 94. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
  - 95. The Zimmer Defendants deny the allegations in Paragraph 95 of the Complaint.
  - 96. The Zimmer Defendants deny the allegations in Paragraph 96 of the Complaint.
  - 97. The Zimmer Defendants deny the allegations in Paragraph 97 of the Complaint.
  - 98. The Zimmer Defendants deny the allegations in Paragraph 98 of the Complaint.
  - 99. The Zimmer Defendants deny the allegations in Paragraph 99 of the Complaint.
  - 100. The Zimmer Defendants deny the allegations in Paragraph 100 of the Complaint.
  - 101. The Zimmer Defendants deny the allegations in Paragraph 101 of the Complaint.
  - 102. The Zimmer Defendants deny the allegations in Paragraph 102 of the Complaint.
  - 103. The Zimmer Defendants deny the allegations in Paragraph 103 of the Complaint.

# COUNT VIII FRAUDULENT CONCEALMENT

- 104. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
  - 105. The Zimmer Defendants deny the allegations in Paragraph 105 of the Complaint.
  - 106. The Zimmer Defendants deny the allegations in Paragraph 106 of the Complaint.
  - 107. The Zimmer Defendants deny the allegations in Paragraph 107 of the Complaint.
  - 108. The Zimmer Defendants deny the allegations in Paragraph 108 of the Complaint.

- 109. The Zimmer Defendants deny the allegations in Paragraph 109 of the Complaint.
- 110. The Zimmer Defendants deny the allegations in Paragraph 110 of the Complaint.
- 111. The Zimmer Defendants deny the allegations in Paragraph 111 of the Complaint.
- 112. The Zimmer Defendants deny the allegations in Paragraph 112 of the Complaint.
- 113. The Zimmer Defendants deny the allegations in Paragraph 113 of the Complaint.
- 114. The Zimmer Defendants deny the allegations in Paragraph 114 of the Complaint.

# COUNT IX NEGLIGENT MISREPRESENTATION

- 115. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
  - 116. The Zimmer Defendants deny the allegations in Paragraph 116 of the Complaint.
  - 117. The Zimmer Defendants deny the allegations in Paragraph 117 of the Complaint.
  - 118. The Zimmer Defendants deny the allegations in Paragraph 118 of the Complaint.
  - 119. The Zimmer Defendants deny the allegations in Paragraph 119 of the Complaint.
  - 120. The Zimmer Defendants deny the allegations in Paragraph 120 of the Complaint.
  - 121. The Zimmer Defendants deny the allegations in Paragraph 121 of the Complaint.
  - 122. The Zimmer Defendants deny the allegations in Paragraph 122 of the Complaint.
  - 123. The Zimmer Defendants deny the allegations in Paragraph 123 of the Complaint.

# COUNT X LOSS OF CONSORTIUM

- 124. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
- 125. The Zimmer Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 125 of the Complaint and, therefore, deny them.

- 126. The Zimmer Defendants deny the allegations in Paragraph 126 of the Complaint.
- 127. The Zimmer Defendants deny the allegations in Paragraph 127 of the Complaint.
- 128. The Zimmer Defendants deny that Plaintiffs are entitled to any relief demanded in Paragraph 128 of the Complaint.

# COUNT XI PUNITIVE DAMAGES

- 129. The Zimmer Defendants repeat, reallege, and incorporate their responses to each and every paragraph in this Answer as if fully set forth herein.
  - 130. The Zimmer Defendants deny the allegations in Paragraph 130 of the Complaint.
  - 131. The Zimmer Defendants deny the allegations in Paragraph 131 of the Complaint.
- 132. The Zimmer Defendants deny each and every allegation in the Complaint unless expressly admitted or otherwise answered herein.

WHEREFORE, the Zimmer Defendants deny that Plaintiffs are entitled to any relief demanded in the Complaint.

#### **GENERAL DENIAL**

Any remaining allegations neither admitted nor denied are hereby expressly denied.

#### **SECOND DEFENSE**

The Complaint fails to state a claim for which relief may be granted against the Zimmer Defendants.

#### THIRD DEFENSE

The Zimmer Defendants state that Zimmer Holdings, Inc., and Zimmer Orthopaedic Surgical Products, Inc., are not proper parties in the case.

#### **FOURTH DEFENSE**

If Plaintiffs sustained injuries or incurred expenses as alleged, their injuries or expenses were caused in whole or in part by the conduct of one or more persons or entities for whose conduct the Zimmer Defendants were not responsible and with whom the Zimmer Defendants have no legal connection.

#### FIFTH DEFENSE

Any amount that Plaintiffs claim as compensatory damages, if the claims for such amounts are not entirely barred, must be diminished proportionately by the fault of Plaintiffs and the fault of all others who caused or contributed to cause the harm.

# **SIXTH DEFENSE**

If Plaintiffs sustained injuries or incurred expenses as alleged, their injuries or expenses were the result of intervening and/or superseding causes, and not as a result of the Zimmer Defendants' alleged acts or omissions.

#### **SEVENTH DEFENSE**

Plaintiffs cannot recover under the Complaint because the Zimmer Defendants complied with all applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States, State of New York, or by an agency of the United States or the State of New York.

#### EIGHTH DEFENSE

Any claims by Plaintiffs for inadequate warnings are controlled by and barred under the learned intermediary doctrine.

#### **NINTH DEFENSE**

Plaintiffs cannot recover under the Complaint because the Zimmer Defendants' products were in conformity with the generally recognized state of the art at the time they were designed, manufactured, packaged, and labeled.

#### **TENTH DEFENSE**

If Plaintiffs sustained injuries or incurred expenses as alleged, their injuries or expenses were caused by the misuse of the products, and the misuse could not have been intended or reasonably foreseen by the Zimmer Defendants.

#### **ELEVENTH DEFENSE**

If Plaintiffs sustained injuries or incurred expenses as alleged, their injuries or expenses were caused by a modification or alteration of the products, and the modification or alteration was not reasonably expected by the Zimmer Defendants.

#### TWELFTH DEFENSE

The Plaintiffs failed to plead fraud with particularity as required by F.R.C.P. 9(b).

### **THIRTEENTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of federal preemption.

# **FOURTEENTH DEFENSE**

Any claim or cause of action that Plaintiffs may have had is time barred by applicable periods of prescription, preemption, and/or statute of limitations.

#### FIFTEENTH DEFENSE

The Zimmer Defendants aver that Plaintiffs had a duty to mitigate any damages

Plaintiffs claim to have suffered, which failure bars or reduces any recovery by Plaintiffs herein.

#### **SIXTEENTH DEFENSE**

The Zimmer Defendants plead Act of God, force majeure, or unavoidable accident in defense of Plaintiffs' claims.

#### **SEVENTEENTH DEFENSE**

The Zimmer Defendants aver that any product made the subject of this proceeding posed no unreasonable risk of harm and is not otherwise defective.

# **EIGHTEENTH DEFENSE**

The Zimmer Defendants aver that any product made the subject of this proceeding was not in a dangerous, defective, or unsafe condition when it left the possession, custody, or control of the Zimmer Defendants.

#### **NINETEENTH DEFENSE**

The Zimmer Defendants allege that any product made the subject of this proceeding was not in a dangerous, defective, or unsafe condition as a result of any action or inaction on the part of the Zimmer Defendants.

### TWENTIETH DEFENSE

In the event any product made the subject of this proceeding is found to have posed an unreasonable risk of harm, is found to have lacked adequate warnings, or is found to be otherwise defective, all of which is denied, then the Zimmer Defendants assert that it did not know and in light of scientific and technological knowledge reasonably available, could not have known of the design characteristic that caused the damages complained of or the danger of such characteristic or the alternative design sought to be proven by Plaintiffs.

#### TWENTY-FIRST DEFENSE

In the event that any product made the subject of this proceeding is found to have posed an unreasonable risk of harm, is found to have lacked adequate warnings, or is found to be otherwise defective, all of which is denied, then the Zimmer Defendants asserts that any alternative design sought to be proven by Plaintiffs was not feasible in light of scientific, technological knowledge reasonably available at the time of the manufacture, or that exists in economic practicality.

#### TWENTY-SECOND DEFENSE

In the event that any product made the subject of this proceeding is found to have posed an unreasonable risk of harm, is found to have lacked adequate warnings, or is found to be otherwise defective, all of which is denied, then the Zimmer Defendants assert that no warning was necessary, as any dangers were open and obvious, and/or the product was sold to, leased to, or being used by a sophisticated user.

# **TWENTY-THIRD DEFENSE**

Any and all warranties were voided and/or waived by the improper operation, modification and/or failure to inspect or maintain the product made the subject of this proceeding by Plaintiffs and/or others for whom the Zimmer Defendants were not responsible.

#### TWENTY-FOURTH DEFENSE

To the extent that Plaintiffs make claims for breach of warranties, the Zimmer Defendants assert that such claims are barred by Plaintiffs' failure to comply with notice provisions required by New York law and because there is no privity of contract between Plaintiffs and the Zimmer Defendants. The Zimmer Defendants further assert all defenses and presumptions provided by the New York Uniform Commercial Code.

#### TWENTY-FIFTH DEFENSE

Plaintiffs had full knowledge of, accepted, and/or assumed all risks and possible adverse effects related to the use of any product at issue in this matter. Plaintiffs' recovery, therefore, is barred, diminished, reduced, or offset under the principles of assumption of the risk and/or informed consent.

# TWENTY-SIXTH DEFENSE

The product in question is a prescription medical device that is reasonably safe because reasonable health care providers prescribed the device for a class of patients, knowing the device's foreseeable risks and therapeutic benefits.

# TWENTY-SEVENTH DEFENSE

The Complaint fails to state a claim for punitive damages upon which relief can be granted.

#### TWENTY-EIGHTH DEFENSE

The imposition of punitive damages against the Zimmer Defendants would violate their constitutional rights under the following provisions of the United States Constitution and the comparable provisions of the New York, Delaware, Indiana, and Ohio Constitutions: The Due Process Clauses in the Fifth and Fourteenth Amendments, the Double Jeopardy Clause in the Fifth Amendment, and the Commerce Clause.

#### TWENTY-NINTH DEFENSE

Plaintiffs' claims are barred to the extent the injuries alleged in the Complaint resulted from a preexisting and/or unrelated medical and/or idiosyncratic reaction to any Zimmer *NexGen* product and not from any act or omission by any of the Zimmer Defendants or by any defect in any Zimmer *NexGen* product.

#### THIRTIETH DEFENSE

The Zimmer Defendants hereby give notice that they intend to rely upon any other defense that may become available or appear during the discovery proceedings in this case and hereby reserves its right to amend this answer to assert any such defense.

WHEREFORE, the Zimmer Defendants respectfully request judgment in their favor, dismissal of the Complaint on the merits with prejudice, costs of this action, attorneys' fees, and all other appropriate relief to which they may be entitled.

Dated: New York, New York

August 16, 2011

Respectfully submitted,

#### /s/Phoebe A. Wilkinson

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# **CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing ANSWER TO FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL BY DEFENDANTS ZIMMER, INC., ZIMMER HOLDINGS, INC., AND ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC., has been served via the Court's electronic filing system on the 16<sup>th</sup> day of August, 2011, upon the following counsel of record:

David Rosenband Ellen Relkin WEITZ & LUXENBERG, P.C. 700 Broadway New York, NY 10003

/s/ Phoebe A. Wilkinson